

**INSERT HOSPITAL/HEALTH SERVICE LOGO**

**Queensland Renal Biopsy Registry**

**Participant Information Sheet and Consent Form**

**Site Name:** **Site-specific**

**Title:** **Queensland Renal Biopsy Registry**

**Protocol Version:** **Version 1.2 dated 15<sup>th</sup> of January, 2018**

**Principal Investigator:** **Site-specific**

**Associate investigators** **(Site-specific):**

**Location:** **Site-specific**

This Participant Information Sheet and Consent Form tells you about this project, the Queensland Renal Biopsy Registry. Knowing what is involved will help you decide if you want to take part in the Registry.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend, or local doctor.

Participation in this registry is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part. If you decide you do want to take part in the registry, you will be asked to sign the consent section of this form.

By signing the consent section you are telling us that you:

- Understand what you have read
- Consent to take part in the registry and consent to the research that is described
- Consent to the use of your de-identified personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

**1. What is Queensland Renal Biopsy Registry (QRBR)?**

QRBR is a registry established by kidney specialists across Queensland in collaboration with Chronic Kidney Disease in Queensland (CKD.QLD) and Pathology Queensland and is supported by the Queensland Health State-wide Clinical Renal Network. CKD. QLD is an organization established out of collaboration between the Centre for Chronic Disease at The University of Queensland and Queensland Health Renal Medicine Services. Material and financial support comes for this research comes from many sources. The initiative is currently supported by freely donated time and effort of the kidney specialists who support this research, the Director of the Centre for Chronic Disease and other professionals.

**2. What is the Queensland Renal Biopsy Registry – Purpose and Background?**

Each kidney is made of about one million tiny structures called nephrons. Kidneys fail when diseases damage these nephrons. Kidney injury may also occur for a short while which is

called an acute kidney injury (AKI), or kidney function may worsen over months to years which is known as chronic kidney disease (CKD).

People suffering from AKI may recover their kidney function with treatment but in some cases, AKI may lead to CKD. About 1 in every 10 Australian adults have CKD. A small number of these people with CKD may progress to end stage kidney disease (ESKD) which is when the kidneys are no longer able to support life. With access to kidney specialists, these people may choose to have a renal replacement therapy (dialysis or kidney transplantation).

The three most common causes of kidney disease requiring dialysis are diabetes, glomerulonephritis (injury to the part of the kidney that filters waste products from our bodies) and hypertension (high blood pressure). Kidney doctors often perform kidney biopsies (take and examine a very small piece of kidney tissue) to identify the type of disease and then to help prescribe the best care to that person. A kidney biopsy is sometimes used to check on the extent of the kidney damage and to see how well a person's treatment is working.

The care of people with kidney disease is varied. Currently there is not enough information on management and treatment outcomes for patients as a whole that gives information about the benefits (or not) of these variations of care. In many developed countries renal biopsy registries have been initiated to address these issues. There is no similar registry existing in Australia. We therefore aim to establish a renal biopsy registry, commencing in Queensland, with the vision of becoming a national Registry. The purpose of this registry is to collect detailed clinical, management and outcome information of patients with biopsy-proven kidney disease. Analysis of the registry, with large numbers of patients, will provide opportunities for better understanding of the course and outcomes of these patients. This information will also be used to help formulate Australian guidelines for kidney disease management.

### **3. What information is collected about you?**

You are invited to take part in the Queensland Renal Biopsy Registry (QRBR) as you have been diagnosed with kidney disease and have previously had a kidney biopsy.

The information we will collect for the QRBR includes your name, age, gender, racial origin, weight at birth, postcode, current and past occupations, hospital treatment/management, medical conditions and history, like diabetes and heart disease and who and when you were referred to your kidney doctor.

Information about the type of kidney treatment you are receiving, which includes medications, renal replacement therapy (when started), and any outcomes eg any improvement in your kidney function, will be included in the Registry.

We will also collect the results of pathology tests, for example blood, urine and kidney biopsy tests, and x-ray results that have been ordered as part of your usual routine care.

Information about you may be obtained from your health records held at this health service, other health services and health-related databases for the purpose of this research.

By signing the consent form you agree to the research team accessing your health records (hard charts or electronic) if it is relevant to your participation in this research project.

Your health records and any information obtained during the research project are subject to review and verification by research personnel and research auditors. By signing the Consent Form, you authorize the release of, or access to, this confidential information by these authorities.

#### **4. Is personal data ever released?**

The identity of people in the Registry **IS NOT** released publicly or in any reports. Measures have been put into place to ensure the security of all collected information. These include password protection of all computers and all these are kept in secure locked locations on Queensland Health government property at each participating hospital. The primary central data repository will be located within the secured electronic filing system of the Metro North Kidney Health Service (Royal Brisbane and Women's Hospital).

#### **5. What is this information used for?**

The information is used for improvement of the quality of care of people with kidney disease, to study kidney disease, and to support the development of Australian health service guidelines of people with kidney disease. We propose to release reports on a variety of topics, including an Annual Report on the amount and treatment of biopsy proven kidney disease in Queensland. Individual patients will not be identified in these reports.

From time to time, results will also be produced for renal units, government health departments and industry, concentrating on particular aspects of kidney management e.g.: the progression of kidney disease and its management and treatments.

The information produced from the Registry may be used for future research in kidney disease. However, any research proposal based on the information collected from you will require additional approval from Human Research Ethics committees.

#### **6. Can you see what personal information the Queensland Renal Biopsy Registry collects and the reports that it produces?**

Individuals are able to view their own information on request at the time of their clinic visit. You can request changes, if you believe it is not correct. You may also choose not to have your treatment included in this Registry by telling your kidney specialist and not signing this Consent Form.

You may also choose not to have some information, e.g. racial origin, recorded. However, if your information is not included in the Registry, the ability to compare results in Queensland across various units or to analyse the results of different treatments and for different patient types, e.g. patients with diabetes, will be less complete.

De-identified reports and other material produced by Queensland Renal Biopsy Registry will be available to all participating unit and housed on the Queensland Renal Biopsy Registry Website or they can be sent to you on request to your address. Your kidney specialist will also have access to all reports.

#### **7. Your participation and alternatives:**

##### **i. Possible benefits:**

There may not be direct benefits associated with participation in the Registry. The use of information contained within the Registry is for future research and may be of future benefit to patients with kidney disease in general. Current participants in the Registry may be informed of future research studies, including clinical trials, specific to their type of kidney disease. Each of these would require their own Patient Information and Consent Form, and Human Research Ethics Committee approval.

**ii. Possible risks and disadvantages:**

You will be required to attend the Clinic for approximately thirty minutes to one hour where you will be asked some questions and examined as per normal clinical practice. The Clinic is where you will be receiving your ongoing management of your kidney disease.

**8. In the event of new information arises during this research project?**

Participants in the Registry may be informed of future research studies involving kidney disease for which they may be eligible. If any new information arises during this research project that may have a direct implication on your health, this information will be communicated to you and your treating doctor, via the Principal Investigator at your site, so that he/she can advise you on the best treatment options.

**9. Other treatment during this research project:**

The Registry is an observational study and intends to monitor for any long-term outcomes, especially in relation to treatment and outcomes of your kidney disease. You may go onto treatment that is part of standard of kidney care, or be offered enrollment in a therapeutic trial.

**10. Consequences of withdrawal from the Registry project:**

You can decide not to be in this Registry. Your treatment will in no way be affected if you choose not to participate in the Registry or if you decide to withdraw at any time. If you withdraw, all of your individual information will be removed from the Registry with the exception of your name, date of birth, hospital number, renal doctor and Registry ID, so that you will not be contacted in the future. For data that may have already been included into a larger data set for analysis and in circumstance where it is not possible to exclude individual data points after their inclusion, this data may be used by the researcher. All patient data will remain de-identified.

A partial opt-out means no further request will be made from the research team but information collected up to the time of withdrawal may be used as de-identified data.

To withdraw from the study, please contact the Principal Investigator, **Site-specific**. A “withdrawal of consent form” is also included in this Information and Consent document.

**11. Unexpected termination of the Queensland Renal Biopsy Registry:**

As the continuation of this Registry is dependent on ongoing funding, and while it is intended that this is a long term Registry, lack of funding may result in its early closure. Patient information may be kept centrally, for an indefinite period but with Ethic approval, and in an electronically protected form.

If you wish to discuss any of the issues raised here, please let your doctors know or telephone Queensland Renal Biopsy Registry direct on (07) 3646 8576.

You may also write to us:

Queensland Renal Biopsy Registry,  
c/- Department of Renal Medicine,  
Royal Brisbane and Women’s Hospital,  
Herston, Brisbane, QLD 4029

## **12. Privacy, Confidentiality and Disclosure of Information:**

All your information will be de-identified so that only the medical team at your kidney health service, and central research staff appointed to manage the Registry and health-related databases, can have access to your true identity. All other researchers will only be provided de-identified information that is based on your study unique ID (Registry ID). The information entered into the electronic Registry will have information that can directly identify you, such as your name, address and hospital number, but this environment is highly secure and will be similar to your health record kept at the hospital or clinic, and can only be accessed by the authorised personnel directly involved with your care.

Your de-identified (coded) health information may be shared in confidence with other doctors or researchers, which may include but is not limited to different research institutions, other registries, hospitals, private entities, government or other health services from Australia or overseas, for research, reporting or statistical purposes, provided there is written approval for this sharing by the Queensland Renal Biopsy Steering Committee and the Research Ethics Committee that has approved this Registry. Your information will be kept indefinitely but for a minimum of 15 years at least, in a secure electronic form, and used in any current or future research that has been reviewed and approved by the Research Ethics Committee.

Where relevant, results of Registry research questions will be published, with acknowledgement of the Queensland Renal Biopsy Registry and of patients (de-identified) who have participated.

## **13. Access to Information:**

All routine clinical test results including your kidney biopsy will be available to you and you're treating doctors through your renal clinic. Copies of any publications arising from information obtained from the Registry can be made available to you. In any publication and/or presentations, information will be provided in such a way that you cannot be identified.

In accordance with relevant Australian and State privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected.

## **14. Research funding**

This is an investigator-initiated multi-center registry, endorsed by the Queensland Renal Biopsy Registry Steering Committee, currently supported by in-kind donations of their time by kidney specialists in Queensland. The ongoing funding of this project may come from a combination of University, National Health and Medical Research Council of Australia (NHMRC), other granting organisations and/or industry partners.

## **15. Human Research Ethics Committee (HREC) Review**

This research has been reviewed and approved by the Human Research Ethics Committee-at Royal Brisbane and Women's Hospital HREC (EC00172). The research for the QRBR will be carried out according to the National Statement on Ethical Conduct in Human Research (March 2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**For questions, complaints or concerns:**

Should you wish to discuss the study with someone not directly involved, in particular in relation to matters concerning program policies, information about conduct of the program or your rights as a participant, or should you wish to make an independent complaint, you can contact:

Coordinator or Chairperson,  
RBWH Human Research Ethics Committee (HREC)  
Metro North Hospital and Health Service,  
P: (07) 3646 5490  
Email: [RBWH-Ethics@health.qld.gov.au](mailto:RBWH-Ethics@health.qld.gov.au)  
Website: [www.health.qld.gov.au/rbwh/research/hrec.asp](http://www.health.qld.gov.au/rbwh/research/hrec.asp)

**16. Complaint and further information:**

If you require further clinical information or have any complaints about any aspect of the project, the way it is being conducted at **Site-specific** or any questions about your rights as a research participant, then you may contact:

Research participant rights –

Coordinator or Chairperson,  
RBWH Human Research Ethics Committee (HREC)  
Metro North Hospital and Health Service,  
P: (07) 3646 5490  
Email: [RBWH-Ethics@health.qld.gov.au](mailto:RBWH-Ethics@health.qld.gov.au)  
Website: [www.health.qld.gov.au/rbwh/research/hrec.asp](http://www.health.qld.gov.au/rbwh/research/hrec.asp)

Clinical Contact Person –

Name: **Site-specific**  
Position: **Site-specific**  
Telephone: **Site-specific**  
Email: **Site-specific**

Complaints Contact Person –

Name: **Site-specific**  
Position: **Site-specific RGO**  
Telephone: **Site-specific**  
Email: **Site-specific**

You will need to tell **Site-specific** the name of one of the researchers given at the top of this information sheet.

**INSERT HOSPITAL/HEALTH SERVICE LOGO**

**Participant Consent Form (Adult)**

**Title: Queensland Renal Biopsy Registry**  
**Protocol Version: Version 1.2 dated 15/01/2018**  
**Principal Investigator Site-specific**  
**Associate investigators Site-specific**  
**Location: Site specific Site-specific**

**Declaration by Participant**

- I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described in the project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to participate in this Registry as described and understand that I am free to withdraw at any time without affecting my future health care.
- I give permission for my doctors, other health professionals, hospitals, health departments or laboratories outside this hospital to release information to the Registry (QRBR) about my condition and treatment for the purposes of this project. I understand that such information will remain confidential.
- I understand that I will be given a signed copy of this document to keep.

I give my consent to participate in this Registry Study by signing this form and also declare that I understand what is involved.

**Participant's Name (printed) .....**

**Signature:.....Date.....**

**Name of Witness to Participant's Signature (printed) .....**

**Signature:.....Date.....**

\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

**Declaration by researcher\*: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.**

**Researcher's Name (printed) .....**

**Signature:.....Date.....**

**\* A senior member of the research team must provide the explanation and provision of information concerning the research project.**

**Note: All parties signing the Consent Form must date their own signature.**

**INSERT HOSPITAL/HEALTH SERVICE LOGO**

**Participant Consent Form (Parent and Guardian)**

**Title: Queensland Renal Biopsy Registry**

**Protocol Version: Version 1.2 dated 15/01/2018**

**Principal Investigator Site-specific**

**Associate investigators Site-specific**

**Location: Site specific Site-specific**

**Declaration by Parent/Guardian**

- I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described in the project.
- I freely agree to \_\_\_\_\_(the child) participating in this research project as described and understand that I am free to withdraw them at any time without affecting their future health care.
- I understand that with my consent information regarding \_\_\_\_\_ (the child) will be collected and stored in the Queensland Renal Biopsy Registry, for use as described in this document.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I give permission for the child’s doctors, other health professionals, hospitals, health departments or laboratories outside this hospital to release information to **Site-specific** or the research team of Queensland Renal Biopsy Registry concerning \_\_\_\_\_ (the child’s) condition and treatment for the purposes of this project. I understand that such information will remain confidential.
- I understand that I will be given a signed copy of this document to keep.

**Child’s Name (printed) .....**

**Child’s Signature (optional):.....**

**Parent or Guardian’s Name (printed) .....**

**Parent or Guardian’s Signature:.....**

**Date.....**

**Name of Witness to Participant’s Signature (printed) .....**

**Signature:.....Date.....**

\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

**Declaration by researcher\*: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.**

**Researcher’s Name (printed) .....**

**Signature:.....Date.....**

**\* A senior member of the research team must provide the explanation and provision of information concerning the research project. Note: All parties signing the Consent Form must date their own signature.**



**INSERT HOSPITAL/HEALTH SERVICE LOGO**

**Form for Withdrawal of Participation (Adults)**

**Title: Queensland Renal Biopsy Registry**  
**Protocol Version: Version 1.2 dated 15/01/2018**  
**Principal Investigator Site-specific**  
**Associate investigators Site-specific**  
**Location: Site specific Site-specific**

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with **[Insert Hospital: Site-Specific]**.

Tick whichever of the following is applicable:

I do not want any further involvement or follow up in regard to this research project and I agree that all my clinical data collected up to the time of withdrawal may be used as de-identified data. (Partial Opt-Out)

**OR**

I do not want any further involvement or follow up in regard to this research project and I request that all my clinical data be deleted, such that they are not used for any future Registry research projects. (Full Opt-Out)

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____
Signature _____ Date _____

**Declaration by Study Doctor/Senior Researcher<sup>†</sup>**

I have given a verbal explanation of withdrawal from the Registry research project, and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher <sup>†</sup> (please print) _____
Signature _____ Date _____

**<sup>†</sup> A senior member of the research team must provide the explanation of, and information concerning, the research project.**

Note: All parties signing the consent section must date their own signature.

**INSERT HOSPITAL/HEALTH SERVICE LOGO**

**Form for Withdrawal of Participation (Parent/Guardian)**

**Title: Queensland Renal Biopsy Registry**  
**Protocol Version: Version 1.2 dated 15/01/2018**  
**Principal Investigator Site-specific**  
**Associate investigators Site-specific**  
**Location: Site specific Site-specific**

**Declaration by Parent/Guardian**

I wish to withdraw the child from participation in the above research project and understand that such withdrawal will not affect the child's routine treatment, my relationship with those treating me or my relationship with **[Insert Hospital: Site-Specific]**.

Tick whichever of the following is applicable:

I do not want any further involvement or follow up of the child in regard to this research project and I agree that all the child's clinical data collected up to the time of withdrawal may be used as de-identified data. (Partial Opt-Out)

**OR**

I do not want any further involvement or follow up of the child in regard to this research project and I request that all the child's clinical data be deleted or destroyed, such that they are not used for any future research projects. (Full Opt-Out)

I understand that I will be given a signed copy of this document to keep.

Name of Child (please _____)
Name of Parent/Guardian (please print) _____
Signature of Parent/Guardian _____ Date _____

**Declaration by Study Doctor/Senior Researcher<sup>†</sup>**

I have given a verbal explanation of withdrawal from the Registry research project and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher <sup>†</sup> (please print) _____
Signature _____ Date _____

**† A senior member of the research team must provide the explanation of, and information concerning, the research project.**

Note: All parties signing the consent section must date their own signature.